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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,577	03/21/2005	Ulrich Speck	WEICKM-44	8523

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EXAMINER	
BOUCHELLE, LAURA A	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
02/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/528,577	SPECK ET AL.	
	Examiner	Art Unit	
	LAURA A. BOUCHELLE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46,49 and 51-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *49 and 55* is/are allowed.

6)☒ Claim(s) *1-15 , 18, 20-25, 27-38, 41-46, 50-54* is/are rejected.

7)☒ Claim(s) *16,17,19,26,39 and 40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/7/09, 1/13/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims **1-9,14, 15, 18, 20, 22-25, 27-29, 37, 38, 41, 42, 44, 45, 51,53** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schultz (US 2004/0224003, which claims priority to Provisional application No. 60/446318 filed Feb. 7, 2003). Schultz discloses a drug formulation for coating medical devices that is immediately released for the selective therapy of specific tissue (page 3, paragraph 0040) comprising an angioplasty balloon, a drug which is lipophilic, water-insoluble and immediately releasable (page 2, paragraph 0023).

4. The balloon may include a stent (page 3, paragraph 0037) or the coating may be provided on a balloon without a stent (page 22, paragraph 0025).

5. The balloon is wrapped which is analogous to folding. The balloon can be deflated and rewrapped and moved to a different location to apply the drug to the second location (page 2, paragraph 0033). Therefore, the coating adheres sufficiently well to resist the forces required for folding without damage.

6. The lipophilic drug may be an inhibitor of cell proliferation such as paclitaxel (page 1, paragraph 0006).

7. The drug is applied in a solution using immersion (page 2, paragraph 0026). Ethanol is used as a solution (page 2, paragraph 0026).

8. The device is sterilized by any known means after it is coated with the drug (paragraph 0026).

9. The device is used to treat vascular disease by opening a passage in the body (page 1, paragraph 0005).

10. Regarding claims 1, Shultz discloses that the drug coating in applied to a standard commercially available angioplasty balloon (page 2, paragraph 0027). It is inherent that a standard angioplasty balloon has a smooth surface. Alternatively, it would be obvious to one of ordinary skill in the art at the time of invention that a standard angioplasty balloon is smooth and therefore the coating is applied to a smooth surface.

11. Regarding claim 6, Shultz discloses that little dissolution or removal of the drug from the surface of the balloon occurs prior to inflation of the balloon in the artery (page 2, paragraph 0031). Therefore, one of ordinary skill in the art would recognize that this is achieved by only coating the area covered by the folds with the drug.

12. Claims **10, 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shultz in view of Desai et al (US 5916596). Claims 10, 30 call for the drug to include amorphous structures with particle sizes ranging from 0.1 to 5 microns. Shultz teaches that the drug is a quick dissolving lipophilic drug such as paclitaxel but fails to disclose the particle size. Desai teaches that it is known in the art to use paclitaxel particles having a diameter of less than one micron so that the drug can be delivered in vivo. See Abstract. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Shultz to have the drug in particles of less than about one micron as taught by Desai so that the drug can be delivered in vivo regardless of its water solubility.

13. Claims **11-13, 31, 32, 36, 52, 54** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shultz in view of Barry et al (US 6306166). Claims 11-13, 31, 32, 36 differ from Shultz in calling for the drug to be embedded in a readily water-soluble matrix, the matrix to be a low molecular weight hydrophilic substance. Barry teaches loading and release of water insoluble drugs such as paclitaxel in a low molecular weight matrix that allows the drug to be adhered to a medical device and still be absorbed into the tissue (Col. 15, lines 16-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Shultz to have the drug embedded in a low molecular weight matrix as taught by Barry so that the drug can have good adhesion to the medical device and be readily absorbed by the tissue.

14. Claims **21, 43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shultz in view of Ding et al (US 6364856). Shultz teaches that the device may be sterilized in any known manner. Claims 21, 43 differ from Shultz in calling for the device to be sterilized using ethylene oxide. Ding teaches a medical device with a coating for controlled drug release similar to that of Shultz, but further including the step of sterilizing the device using ethylene oxide as is well known in the art (Col. 6, lines 57-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Shultz to include the step of sterilizing the device using ethylene oxide as taught by Ding because it is well known that devices to be inserted into a patient need to be sterilized and using ethylene oxide is an established technique for sterilization of medical devices.

15. Claims **33-35** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shultz in view of Barry as applied to claim 31 above, and further in view of Klaveness et al (US 6177061). Claims 33-35 differ from the teachings above in calling for the matrix to be a contrast agent, and the contrast agent is iopromide. Klaveness teaches the use of iopromide in a matrix material so that the matrix can be visualized when it is inside the body using x-ray (Col. 7, lines 14-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Shultz in view of Barry so that the matrix is formed of the contrast agent iopromide as taught by Klaveness so that the substance can be visualized using x-ray.

16. Claim **46** is rejected under 35 U.S.C. 103(a) as being unpatentable over Shultz in view of Bates et al (US 2004/0073284). Claim 46 differs from Shultz in calling for the device to be used

to treat a tumor. Bates teaches that a coated balloon device can be used to treat a variety of conditions including tumors (page 6, paragraph 0055). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Shultz to treat a tumor as taught by Bates because a coated balloon can be used to successfully treat many different conditions.

Allowable Subject Matter

17. Claims 49, 55 are allowed.

18. Claims 16, 17, 19, 26, 39, 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

19. Applicant's arguments, see page 11, filed 12/7/09, with respect to the rejection(s) of claim(s) under Bates have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Shultz.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

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